

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF WEST VIRGINIA  
AT CHARLESTON**

<b>IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION</b>	<b>Master File No. 2:12-MD-02327 MDL No. 2327</b>
<b>THIS DOCUMENT RELATES TO:</b>  <b>THE WAVE 4 CASES LISTED IN DEFENDANTS' EXHIBIT A</b>	<b>JOSEPH R. GOODWIN U.S. DISTRICT JUDGE</b>

**PLAINTIFFS' RESPONSE IN OPPOSITION TO ETHICON'S MOTION  
TO EXCLUDE THE GENERAL OPINIONS AND  
TESTIMONY OF WILLIAM PORTER, M.D.**

Plaintiffs submit the following Memorandum of Law in opposition to the “Motion to Exclude the General Opinions and Testimony of William Porter, M.D.” filed by Defendants Ethicon, Inc. and Johnson & Johnson (collectively “Ethicon”). Ethicon’s Motion should be denied and Dr. Porter’s opinion testimony should be admitted for the following reasons:

**BACKGROUND AND DR. PORTER’S QUALIFICATIONS**

Dr. Porter is a urogynecologist with years of extensive training and practice in the field of female pelvic medicine. Ex. A., Rule 26 Report of Dr. William Porter (“Porter Rule 26 Report”) at 1; *see also* Ex. A at Appendix 2, Curriculum Vitae of Dr. William Porter (“Porter CV”) at 1-3.<sup>1</sup> Dr. Porter graduated from the medical school at Wayne State University. Ex. A at 1. He completed his residency in Obstetrics and Gynecology at the University of Cincinnati. *Id.* He completed a three-year fellowship in Female Pelvic Medicine and Reconstructive Surgery

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<sup>1</sup> As the “general opinions” of Dr. Porter which Ethicon has attacked here do not differ from Plaintiff to Plaintiff, Plaintiffs’ only attach Dr. Porter’s Report in *Christopherson v. Ethicon, Inc.*, Case No. 2:12-cv-04365, as Exhibit A. Plaintiffs’ responsive arguments, however, apply equally to all cases listed Ethicon’s Exhibit A.

(FPMRS). *Id.* He was one of the very first physicians in the United States to receive this certification. *Id.* He has served as a journal reviewer for two reputable medical journals in his field. *Id.* He is a frequent lecturer, teacher, and speaker in the field of urogynecology and reconstructive pelvic surgery. *Id.* Dr. Porter has also taught at many industry-sponsored labs and has consulted with medical device companies in the development and validation of new pelvic floor products. *Id.*

Dr. Porter's surgical training and experience is extensive. He has performed nearly 3,000 pubovaginal slings (synthetic and xenographic) and fascia latta bladder neck slings. *Id.* at 2. He has also performed several thousand vaginal repairs for pelvic organ prolapse. *Id.* Dr. Porter has specifically treated female patients with the Ethicon vaginal mesh products on numerous occasions. *Id.* at 2. Based on Dr. Porter's work as a urogynecologist, he is familiar with medical complications that are generally associated with mesh repair surgery, and is experienced in the recognition, diagnosis, and treatment of patients suffering from complications caused by pelvic mesh products. Ex. A at 2.

Dr. Porter has faced similar *Daubert* challenges before this Court. This Court has repeatedly considered – and consistently rejected – similar arguments for the exclusion of Dr. Porter's testimony in similar pelvic mesh cases. *See, e.g., Bethune v. Boston Scientific Corp.*, No. 2:13-cv-06199, 2016 WL 2983697 \*12-13 (S.D.W.Va. May 20, 2016); *Wilkerson v. Boston Scientific Corp.*, No. 2:13-cv-04505, 2015 WL 2087048 at \*19-21 (S.D.W.Va. May 5, 2015); *Winebarger v. Boston Scientific Corp.*, No. 2:13-cv-28892 at \*25-27 (S.D.W.Va. April 24, 2015); *see also In Re: Mentor Corp. ObTape Transobturator Sling Products Liability Litigation*, 711 F.Supp.2d 1348, 1370 (M.D. Ga. 2010). Dr. Porter's testimony concerning the Wave 4 Plaintiffs' cases is not meaningfully different from testimony that was at issue in those prior cases.

With regard to his qualifications, this Court has noted, “Dr. Porter’s experience in the area of pelvic medicine is undeniable: Over the last 15 years, he has performed nearly 3,000 surgeries using pubovaginal slings, both synthetic and xenographic, several thousand POP surgeries using native tissue and other materials, and more than 100 mesh explant surgeries.” *Winebarger v. Boston Scientific Corp.*, Civil Action No. 2:13-cv-28892 [Dkt. No. 100] at \*47 (S.D. W. Va. April 24, 2015) (internal citations omitted).

Dr. Porter’s background, training, and expertise in the field of Urogynecology and female pelvic medicine is undeniable. Dr. Porter is more than qualified to offer his general expert opinions in these Wave 4 cases.

### **LEGAL STANDARD**

The task of evaluating the reliability of expert testimony is uniquely entrusted to the district court. *Daubert v. Merrell Dow Pharmaceuticals, Inc.* 509 U.S. 579, 589 (1993). Under Federal Rule of Evidence 702 if scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education may testify thereto in the form of an opinion or otherwise, provided the testimony (1) is “based upon sufficient facts or data” and (2) is “the product of reliable principles and methods,” (3) which have been reliably applied “to the facts of the case.” *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 601 (S.D.W. Va. 2013).

Rule 702 must be applied flexibly, so as to uphold the general framework of the Rules which favor the admissibility of evidence over non-admissibility. *See Daubert*, 509 U.S. at 588, 594. In short, “the rejection of expert testimony is the exception rather than the rule.” *U.S. v. Stanley*, No. 12-4572, 2013 WL 3770713 at \*1 (4th Cir. July 19, 2013) (internal quotations omitted). The proponent of expert testimony does not have the burden to “prove” anything. He

must, however, “come forward with evidence from which the court can determine that the proffered testimony is properly admissible.” *Maryland Cas. Co. v. Thism–O– Disc, Inc.*, 137 F.3d 780, 783 (4th Cir.1998). All *Daubert* demands is that the trial judge make a “preliminary assessment” of whether the proffered testimony is both reliable and helpful. *In re C.R. Bard, Inc.* 948 F. Supp. 2d at 601.

### **ARGUMENT**

Ethicon challenges Dr. Porter’s general opinions on the following five grounds: (1) they are “largely regurgitations of hearsay”; (2) they reference opinions of Dr. Elliott and Dr. Rosenzweig which Ethicon has separately moved to exclude; (3) his “dyspareunia rate” opinions are unreliable because he “cherry picked” the scientific studies he relies upon; (4) his opinions on “common mesh complications” and “chronic inflammation” are unsupported; and (5) he is not qualified to opine on biocompatibility, materials, or design. Defs’ Br. at 3-7. Each of these assertions fails for the reasons below.

#### **I. Dr. Porter’s opinions are not “inadmissible hearsay”—and even if they were, they should not be excluded on *Daubert***

Ethicon attacks four of Dr. Porter’s opinions by making the absurd assertion that: “[h]is Opinions 2, 4, 5, and 6...are mere recitations of scientific literature, opinions or other plaintiff-experts, and statements of an Ethicon employee. These types of recitations are not expert opinions.” Defs’ Br. at 4. Apparently, according to Ethicon, an expert like Dr. Parker cannot rely upon or discuss scientific literature or the testimony of other witnesses—including Ethicon’s own employees—when rendering and supporting his opinions. Defs’ Br. at 4. That is simply not the law.

In this section, Ethicon *seems to* make two arguments: (1) these opinions are “inadmissible hearsay”; and (2) the opinions simply “parrot” what is in the documents and testimony of others.<sup>2</sup> First, as Ethicon has been previously instructed by this Court—on dozens of occasions at this point—its ‘hearsay’ arguments are not properly considered on a *Daubert* motion:

Further, if Ethicon contends that certain statements are inadmissible hearsay, it may object to them at trial. A *Daubert* motion is not the proper method of excluding hearsay. Therefore, these opinions are not excluded.

*In re Ethicon, Inc.*, 2014 U.S. Dist. LEXIS 15351 (S.D. W. Va. Jan. 15, 2014); *see also, e.g., In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2017 U.S. Dist. LEXIS 55340 (S.D. W. Va. Apr. 10, 2017) (“In these *Daubert* motions, the parties have addressed tertiary evidentiary matters like whether certain statements should be excluded as hearsay. The court will not exclude an expert simply because a statement he or she discussed may constitute hearsay. Hearsay objections are more appropriately raised at trial.”)

Second, Dr. Porter does not simply “parrot” the opinions of others—he references relevant scientific literature and testimony as support for his own opinions. Tellingly, in this section, Ethicon does not cite to a single page of Dr. Porter’s report, a single line of testimony (his own or that of any other person), or a single document that Dr. Porter is purportedly “regurgitate[ing].” Defs’ Br. at 4-5. For that reason alone, Ethicon’s argument should be rejected. In its Introduction section, Ethicon makes reference to Dr. Porter’s reliance on several scientific studies (Meyer *et al*, Aperin *et al*, and Porter *et al*). Defs’ Br. at 2-3. But by doing so Dr. Porter does not “parrot the ideas” of others—he merely cites scientific literature supporting his own opinions and conclusions. *In re Mentor Corp. ObTape Transobturator Sling Prods. Liab. Litig.*, 711 F. Supp. 2d 1348, 1370 (M.D. Ga. Apr. 22, 2010) (“...these experts [including Dr. Porter] are not simply

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<sup>2</sup> While the section heading refers to the opinions as “inadmissible hearsay,” Ethicon makes no reference to “hearsay” or Rule 802 in the body of this section. Instead, the body of Ethicon’s argument asserts Dr. Porter’s identified opinions are not proper expert opinion under Rule 702.

parroting published adverse event data. They use that data as confirmation of their own experience using ObTape or treating ObTape patients.”). Similarly, Dr. Porter does not simply regurgitate the opinions of Drs. Elliott and Rosenzweig—or those of Ethicon employee Daniel Burkley—he uses them as further support for his own findings.

As this Court has repeatedly held, under *Daubert*, a court’s reliability determination requires a consideration of certain factors, such as whether the expert’s opinions are supported by scientific literature and have been accepted by other experts in the scientific community. *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 701 (S.D. W. Va. July 8, 2014). Ethicon’s assertion that Dr. Porter’s opinions should be excluded *because* he cites to such support is just silly.

**II. Dr. Porter does not rely solely on Dr. Elliot’s or Dr. Rosenzweig’s well-accepted opinions—and the Court’s exclusion of those other expert’s opinions would not be grounds for exclusion of Dr. Porter’s**

Ethicon points out that it has separately moved to exclude the general opinions of Dr. Elliott and Dr. Rosenzweig—and then asserts: “if the Court deems that Dr. Elliott’s and Dr. Rosenzweig’s opinions are inadmissible, then Dr. Porter may not rely upon those general reports in connection with forming his own opinions....” Defs’ Br. at 5. As a preliminary matter, Plaintiffs must point out Dr. Porter’s report cites to: (1) Dr. Elliott’s opinion that the foreign body reaction and chronic inflammatory response can lead to chronic pain; and (2) Dr. Rosenzweig’s opinion that mesh degradation can lead to chronic foreign body reaction, fibrotic bridging, mesh contracture/shrinkage, fraying, particle loss, roping and curling of the mesh, which contributes to pain. Ex A at 5. All of these opinions have been repeatedly allowed by this Court. So there is no reason to believe that they will be excluded in this round of *Daubert* motions.

In any event, should Dr. Elliott’s or Dr. Rosenzweig’s opinions be excluded, Dr. Porter will not “rely upon those general reports” or “parrot[] their opinions before the jury.” Defs’ Br. at

5. However, the exclusion of those other experts' opinions does not provide an independent basis for excluding Dr. Porter's own opinions.

**III. Dr. Porter's dyspareunia rate opinions are based upon reliable scientific literature**

In his report, Dr. Porter makes reference to the Plaintiffs' claims of dyspareunia, and then cites to the dyspareunia rates found in three separate studies. Ex. A at 4. Ethicon asserts that because he only cited to three studies—and not to the “literally hundreds” of other studies Ethicon deems relevant (but not important enough to list here)—he must have simply ignored this contrary evidence. Defs' Br. at 6. But Ethicon provides absolutely no support for this argument. Ethicon does not cite to a single line of testimony where Dr. Porter says he did not consider the other studies.<sup>3</sup> In fact, Ethicon does not even disclose which study (or studies) it now claims Dr. Porter failed to consider. If Ethicon finds a study that it believes contradicts Dr. Porter's opinions, it is free to ask him about it on cross-examination. But there is no justification for excluding Dr. Porter's opinions based upon Ethicon's vague and unsupported assertions.

**IV. Dr. Porter's opinions on common mesh complications and chronic inflammation are scientifically reliable**

Ethicon seeks to exclude Dr. Porter's opinions on “common mesh-related complications” and the cause and effect of “chronic inflammation.” Defs' Br. at 6-7. Ethicon simply asserts that Dr. Porter has “failed to identify any basis” for these opinions about what occurs in patients after mesh is implanted.

As Dr. Porter said in his report: “[i]n formulating the opinions set forth in this report I have relied on my personal knowledge, education and training, prior experience in treating stress urinary incontinence and pelvic organ prolapse, medical literature, and a review of relevant

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<sup>3</sup> For this reason, Ethicon's citation to the Court's exclusion of Dr. Margolis' opinions in *Tyree v. Boston Sci. Corp.*, 54 F.Supp.3d 501, 520 (S.D.W.Va 2014) is easily distinguishable.

medical records....” Ex. A at 2. Ethicon cites to no testimony, or other grounds, to question the sufficiency of that reasonable basis.

Opinion testimony about common mesh-related complications—including chronic inflammation—is clearly reliable when rendered by an expert urogynecologist with vast clinical and surgical experience like Dr. Porter. Indeed, as this Court has previously held with regard to Dr. Porter’s experience (and his resulting ability to render opinions regarding what occurs *in vivo*):

A witness can be qualified as an expert ‘by knowledge, skill, experience, training, or education.’ As I have held in previous cases, a urogynecologist’s extensive experience with performing mesh implant and explant surgeries can qualify him or her to opine on how the product reacts inside the body. Dr. Porter’s experience in the area of pelvic medicine is undeniable: Over the last 15 years, he has performed nearly 3,000 surgeries using pubovaginal slings, both synthetic and xenographic,; several thousand POP surgeries using native tissue and other materials; and has removed and repaired slings.

*Wilkerson v. Boston Sci. Corp.*, 2015 U.S. Dist. LEXIS 58671, 59-61 (S.D. W. Va. May 5, 2015).

And in the ObTape MDL, Judge Clay agreed that Dr. Porter (and other expert physicians) can rely upon clinical experience to render opinions on how a medical device reacts in the body and the resulting complications. *In re Mentor*, 711 F. Supp. 2d at 1370-1371 (“It is beyond dispute that experience in a field may provide a sufficient foundation for expert testimony.”) (*citing United States v. Frazier*, 387 F.3d 1244, 1260-61 (11th Cir. 2004) (*en banc*)). Ethicon’s unsupported assertion that Dr. Porter has no basis for his opinions falls flat.

**V. Dr. Porter is qualified to offer opinions on transvaginal mesh materials and designs, and how the mesh reacts in the body**

In its final section—in a shotgun fashion—Ethicon asserts that because Dr. Porter is not a biomaterials expert” he is not qualified to “render opinions on biomaterials, polypropylene degradation, chronic body reaction, adequate pore size, adequate weight of polypropylene and biocompatibility of polypropylene.” Defs’ Br. at 7. But Dr. Porter’s opinions do not involve



biomaterials analysis or the mechanics behind such actions. Instead, Dr. Porter is offering an opinion as to the characteristics of mesh *in vivo*, which is based on his extensive experience, training, educational background, and review of well-accepted scientific literature on the subject. *See* Ex. A at 1-2, 4-5.

This same attack on Dr. Porter's urogynecologic opinions (*i.e.* "he is not a biomaterials or polymer expert") has previously, and repeatedly, been rejected by this Court:

**BSC argues that Dr. Porter is unqualified to opine on mesh degradation because he conceded he was not an expert in polymer science or what happens to mesh on a molecular level. However, a urogynecologist's extensive experience with performing mesh implant and explant surgeries—as exhibited by Dr. Porter—can qualify him to opine on how the product reacts inside the body.** Additionally, that he has no experience in polymer science is irrelevant because Dr. Porter is not offering opinions about 'what's happening at the molecular level.' Porter Dep., Dec. 2, 2014, 225:19-227:19. Rather, he considers mesh degradation on a large scale, focusing on the ways a polypropylene mesh product can change after implantation in the human body. His fifteen-year career as a pelvic surgeon qualifies him to render these opinions to the extent they are applicable to his differential diagnosis in this specific case.

*Bethune v. Boston Sci. Corp.*, 2016 U.S. Dist. LEXIS 66449 (S.D. W. Va. May 19, 2016); *Robbins v. Boston Sci. Corp.*, 2016 U.S. Dist. LEXIS 73725 (S.D. W. Va. June 7, 2016) (same). Indeed, this Court has specifically held that Dr. Porter's vast experience allows him to reliably opine on the design of the mesh device, and how it will react or change within the body:

**First, BSC contends that Dr. Porter, who has no experience in polymer science or biomaterials, lacks the qualifications necessary to opine on the degradation of mesh or its tendency to shrink, contract, curl, fold, wrinkle, fragment, or cause pain in general. I disagree.** A witness can be qualified as an expert 'by knowledge, skill, experience, training, or education.' As I have held in previous cases, a urogynecologist's extensive experience with performing mesh implant and explant surgeries can qualify him or her to opine on how the product reacts inside the body. Dr. Porter's experience in the area of pelvic medicine is undeniable: Over the last 15 years, he has performed nearly 3,000 surgeries using pubovaginal slings, both synthetic and xenographic;; several thousand POP surgeries using native tissue and other materials; and has removed and repaired slings. That he has no experience in polymer science is irrelevant because Dr. Porter is not offering opinions about "what's happening at the molecular level." **Rather, he considers mesh degradation on a large scale, focusing on the ways a polypropylene**

**mesh product can change after implantation in the human body. His fifteen-year career as a pelvic surgeon qualifies him to render these opinions to the extent that they are applicable to his differential diagnosis in this specific case.**

*Wilkerson*, 2015 U.S. Dist. LEXIS 58671, 59-61 (emphasis added, citations omitted).<sup>4</sup>

Ethicon makes no mention of this Court's prior rulings with regard to these opinions of Dr. Porter. Nor does it cite to any new testimony—or differences between his current opinions or reports and those previously considered—that would distinguish these prior rulings. Simply put, Dr. Porter's opinions are not 'biomaterials expert' or 'polymer scientist' opinions. They are the same type of opinions this Court has consistently allowed from urogynecologic experts like Dr. Porter throughout this litigation. *See e.g. Wise v. C.R. Bard, Inc.*, 2015 U.S. Dist. LEXIS 14869, at \*18-20, 60-62 (S.D. W. Va. Feb. 7, 2015); *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 707-708, 713 (S.D. W. Va. 2014).<sup>5</sup>

### **CONCLUSION**

For the forgoing reasons, Defendants' motion should be denied in its entirety.

Dated: May 17, 2017

Respectfully submitted,

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<sup>4</sup> Moreover, Dr. Porter's expert opinion is based not only on his extensive medical experience, but also on peer reviewed literature. *See* Ex. A at 2.

<sup>5</sup> Ethicon makes the claim that Dr. Porter "attempts to adopt by reference" the opinions of Dr. Elliott, Dr. Rosenzweig, or (Ethicon employee) Mr. Burkley. Defs' Br. at 7. While Ethicon does not actually argue in this section that such an "adoption by reference" would constitute grounds for excluding Dr. Porter's opinions, Plaintiffs feel it necessary to set the record straight. Dr. Porter does not "adopt" the opinions of any other expert or fact witness. Indeed, despite Ethicon's assertion to the contrary, he makes absolutely no mention of adopting those opinions as his own. He simply makes reference to these supporting facts and opinions in his report. Ex. A at 5.

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**CERTIFICATE OF SERVICE**

I hereby certify that on May 17, 2017, I electronically filed the foregoing document with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/ Edward A. Wallace